

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS**

IN RE: TESTOSTERONE REPLACEMENT  
THERAPY PRODUCTS LIABILITY LITIGATION

This Document Relates To:

*Michael Schleck v. Endo Pharmaceuticals Inc., et al.*,  
Case No. 1:15-cv-09712

MDL No. 2545  
Master Docket Case No. 14-cv-01748  
Honorable Matthew F. Kennelly

**NOTICE OF AFFIRMATIVE DEFENSES OF AUXILIUM PHARMACEUTICALS, LLC  
PURSUANT TO CASE MANAGEMENT ORDER NOS. 56 AND 79**

Defendant, Auxilium Pharmaceuticals, LLC (f/k/a Auxilium Pharmaceuticals, Inc.)

(“Auxilium”), by and through its attorneys, and in accordance with Case Management Order Nos. 56 and 79, hereby provides this Notice of Affirmative Defenses. By alleging the matters set forth below, Auxilium does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters.<sup>1</sup> Auxilium alleges as follows:

1. The causes of action alleged in the Complaint are preempted by the federal statutes and regulations that regulate Testim. Granting the relief requested in the Complaint would impermissibly infringe upon and/or conflict with federal laws, regulations, Food and Drug Administration (“FDA”) guidance and policies -- including 21 U.S.C. § 355, *et seq.* and 21 CFR Part 314, *et seq.* -- in violation of the Supremacy Clause of the United States Constitution (art. VI, cl. 2).

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<sup>1</sup> In Case Management Order No. 65, this Court found that a “defense” which is an “argument about the insufficiency of the plaintiff’s allegations or evidence” is not a defense under the Federal Rules of Civil Procedure and should not be included in the pleadings. Accordingly, Auxilium has excluded such “defenses” (including all defenses related to the learned intermediary doctrine and punitive damages) from this pleading, but reserves the right to re-assert at any time, including at trial, arguments related to issues on which Plaintiff bears the burden of proof.

2. The conduct of Auxilium, as well as the Testim product, including the methods, standards and techniques used in formulating Testim and in issuing warnings and instructions about its use, conformed with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, *et seq.*) and the requirements of the FDA. Moreover, the activities of Auxilium alleged in the Complaint, as well as the design, manufacture and distribution of Testim, conformed with all federal statutes, regulations, FDA guidance and industry standards -- including 21 U.S.C. § 355, *et seq.* and 21 CFR Part 314, *et seq.* -- based upon the state of knowledge and state of the art existing at the relevant time alleged in the Complaint.

3. Plaintiff's claims are barred under Sections 2, 4, *et seq.* of the Restatement (Third) of Torts: Product Liability, because Testim complied with applicable product safety statutes and administrative regulations in that it was approved by the FDA on October 31, 2002, its approval was never withdrawn and at all times, including during the period of Plaintiff's use of Testim, it complied with federal statutes and regulations -- including 21 U.S.C. § 355, *et seq.* and 21 CFR Part 314, *et seq.*

4. The Complaint is subject to the limitations on the doctrine of strict product liability for a purported design defect and breach of warranty as set forth in the Restatement Second of Torts, Section 402A, comment k, where, as here, the manufacturer properly warns of the risks of the medication. *See Buckner v. Allergan Pharms., Inc.*, 400 So. 2d 820 (Fla. App. 1981). Under the framework of comment k, any alleged risks of Testim are unavoidable, the benefits of Testim justify its marketing despite any alleged risks, Testim was and is properly prepared and marketed, and Testim was and is accompanied by proper warnings. Specifically, while Auxilium maintains that Testim is not the cause of Plaintiff's myocardial infarction (heart attack), there was no reasonable evidence of a causal association between Testim and myocardial

infarction (heart attack) and therefore such a risk, if any, was unavoidable at the time of Plaintiff's injury. Additionally, Testim's benefit of raising testosterone levels to the normal range in hypogonadal men justifies the continued marketing and use of Testim despite any alleged risk. Auxilium maintains, and Plaintiff does not dispute, that the Testim used by Plaintiff was properly prepared. Moreover, the Testim label has always identified hematocrit/hemoglobin increases in the Adverse Reactions section of the label and recommended testing hematocrit levels to detect polycythemia. When Mr. Schleck was first prescribed Testim in 2013, Testim was accompanied by a label that included an FDA-approved instruction that stated: "Hemoglobin and hematocrit levels should be checked periodically (to detect polycythemia) in patients on long-term androgen therapy" and an FDA-approved Warning that "Edema, with or without congestive heart failure, may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease." The label further provided that "Liver function, prostate specific antigen (PSA), cholesterol, and high-density lipoprotein (HDL) should be checked periodically."

5. Plaintiff's claims may be barred, in whole or in part, due to the comparative fault of Plaintiff. Fla. St. Ann. § 768.81(2). This includes, but is not limited to, Plaintiff's smoking history and consumption of alcoholic beverages, inconsistent Testim use, as well as his failure to control his severe coronary artery disease, acute coronary syndrome, diabetes, hypertension and high cholesterol, including his decision to take himself off of his hypertension and hyperlipidemia medications.

6. Plaintiff failed to mitigate damages, if any, despite full knowledge of them. This includes, but is not limited to, Plaintiff's failure to participate in cardiac rehabilitation and

continued use of testosterone, consumption of alcoholic beverages and cigar smoking (until at least January 2017) after his myocardial infarction (heart attack).

7. Notwithstanding the claims and contentions of Plaintiff, Plaintiff received and will in the future receive all or substantially all of the benefit from Testim that Plaintiff hoped and intended to receive, including increased testosterone levels, his sex life “got a little better” and his symptoms improved, and to that extent any damages and/or restitution that Plaintiff might be entitled to recover from Auxilium must be correspondingly reduced.

8. If Plaintiff was injured by Testim, those injuries occurred because Plaintiff did not apply Testim consistently. Based on pharmacy records, Mr. Schleck did not regularly use Testim. Such inconsistent use was not reasonably foreseeable to Auxilium.

9. To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are barred for failure of Plaintiff, or Plaintiff’s representative, to give timely notice to Auxilium of any alleged breach of warranty. Fla. St. Ann. § 672.607(3)(a). Moreover, a breach of warranty claim is barred under Florida’s one-year statute of limitations applicable to claims under the Uniform Commercial Code. Fla. St. Ann. § 95.11(5)(c). This action was filed on October 30, 2015, more than one year after Plaintiff’s alleged purchases of Testim.

10. To the extent Plaintiff’s claims relate to Auxilium’s advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitutions of any applicable state, such claims are barred.

11. To the extent Plaintiff's Short-Form Complaint fails to provide Auxilium with sufficient notice as to the claims or facts alleged by Plaintiff, Auxilium gives notice that it intends to rely upon other defenses that may become apparent during the course of the litigation, and reserves the right to amend this pleading to assert any such defenses.

Dated: November 27, 2017

Respectfully Submitted,

By: /s/ Andrew K. Solow

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**CERTIFICATE OF SERVICE**

I, Andrew K. Solow, hereby certify that on November 27, 2017, the foregoing was filed via the Court's CM/ECF system, which will automatically serve and send notification of such filing to all registered attorneys of record.

Dated: November 27, 2017

/s/ Andrew K. Solow  
Andrew K. Solow